IFW
AF

DOCKET NO.: PRES06-00147 **PATENT**
Customer No. 23990

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	:	RONALD A. SCHACHAR
Serial No.	:	09/589,626
Filed	:	June 7, 2000
For	:	SCLERAL PROSTHESIS FOR TREATMENT OF PRESBYOPIA AND OTHER EYE DISORDERS
Group No.	:	3738
Examiner	:	David H. Willse

MAIL STOP APPEAL BRIEF - PATENTS
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

CERTIFICATE OF MAILING BY FIRST CLASS MAIL

Sir:

The undersigned hereby certifies that the following documents:

1. Request for Rehearing Under 37 C.F.R. §41.52; and
2. Postcard receipt.

relating to the above application, were deposited as "First Class Mail" with the United States Postal Service, addressed to Mail Stop Appeal Brief - Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on January 24, 2005.

Date: 1/24/05 Kathy Cedar
Mailer

Date: Jan. 24, 2005 William A. Munck
Reg. No. 39,308

P.O. Drawer 800889
Dallas, Texas 75380
Phone: (972) 628-3600
Fax: (972) 628-3616
E-mail: *wmunck@davismunck.com*

DOCKET NO.: PRES06-00147 **PATENT**
Customer No. 23990

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	:	RONALD A. SCHACHAR
Serial No.	:	09/589,626
Filed	:	June 7, 2000
For	:	SCLERAL PROSTHESIS FOR TREATMENT OF PRESBYOPIA AND OTHER EYE DISORDERS
Group No.	:	3738
Examiner	:	David H. Willse

MAIL STOP APPEAL BRIEF - PATENTS
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

REQUEST FOR REHEARING UNDER 37 C.F.R. § 41.52

This Request for Rehearing Under 37 C.F.R. § 41.52 is filed in reponse to the Decision on Appeal dated November 23, 2004. The due date for the Request for Rehearing is January 23, 2005. Because January 23, 2005 is a Sunday, the due date is extended to Monday, January 24, 2005.

Please consider the Request for Rehearing for the reasons set forth below.

1. BACKGROUND

On November 23, 2004 the Board of Patent Appeals and Interferences (the "Board") issued a Decision on Appeal for Appeal No. 2005-0076, Ex Parte Ronald A. Schachar, for an invention entitled "Scleral Prosthesis for Treatment of Presbyopia and Other Eye Disorder." Claims 1 through 21 were on appeal. Claims 22 through 24 had been previously allowed.

The Decision on Appeal

(1) Reversed the Examiner's rejection of Claims 1-21 under 35 U.S.C. § 101 (for non-statutory subject matter);

(2) Affirmed the Examiner's rejection of Claims 1-7 and Claims 12-17 under 35 U.S.C. § 102(b) (for anticipation); and

(3) Reversed the Examiner's rejection of Claims 8-11 and Claims 21-35 under 35 U.S.C. § 103(a) (for nonobviousness).

The Board held that Claims 1-7 and Claim 12-17 were anticipated by United States Patent No. 5,354,331 issued on October 11, 1994 to Ronald A. Schachar (the '331 Patent). The Appellant respectfully requests the Board to reconsider that portion of the Decision on Appeal that affirmed the Examiner's rejection of Claims 1-7 and Claims 12-17 (the "Rejected Claims")

2. ARGUMENTS

A. THE '331 PATENT DOES NOT ANTICIPATE THE REJECTED CLAIMS

The '331 Patent discloses and claims a prosthetic scleral expansion band for treating presbyopia by increasing the effective working range of the ciliary muscle. Each of the embodiments of the scleral expansion band of the '331 Patent comprises a one-piece circular structure. The word "band" refers to the fact that each of the embodiments of the '331 Patent is in the form of a closed circular ring. Each of sixty three (63) claims of the '331 Patent specifically refers to a "scleral expansion band."

The Rejected Claims are directed to a scleral prosthesis that is not in the form of a closed circular ring. For example, Claim 1 of the Rejected Claims reads as follows:

> 1. A prosthesis that contacts the sclera of an eyeball, said prosthesis comprising a body having a first end and a second end, said body having a planform that expands said contacted sclera to increase the effective working distance of the ciliary muscle of the eyeball.

The Appellant respectfully submits that a scleral prosthesis in the form of a closed circular ring does not have a first end and a second end. Therefore, the '331 Patent does not anticipate the Rejected Claims.

In the Decision on Appeal the Board cited the following portion of the '331 Patent:

> The scleral expansion band may also be made in a plurality of parts that can be assembled prior to use or may be installed separately to form a complete band. The band may be adjustable in circumference. For example, the band may be formed from a strip of material, e.g., metal or synthetic resin, with overlapping ends so that the ends may slide past one another thereby adjusting the circumference of the band. The length of the overlap may be adjusted, for example, by means of a tangential screw mechanism to adjust the circumference of the band and thereby the amount by which the sclera is expanded. ('331 Patent, Column 7, Lines 1-12)

The Board determined that this portion of the '331 Patent anticipated the Rejected Claims (Decision on Appeal, Pages 3-6). The Appellant respectfully requests the Board to reconsider the finding of anticipation in view of the following arguments.

The cited portion of the '331 Patent describes a construction method by which a closed circular ring of the scleral expansion band may be formed before the scleral expansion band is used. The '331 Patent states: "The scleral expansion band may also be made in a plurality of parts that can be assembled prior to use or may be installed separately to form a complete band." ('331 Patent, Column 7, Lines 1-3). It is clear that the "plurality of parts" are assembled to form a "complete band." There is no teaching or suggestion of using the individual parts of the complete scleral expansion band separately (i.e., not formed into a complete ring). On the contrary, the individual parts of the scleral expansion band are always assembled into a complete band. The assembly of the parts may be "prior to use" (i.e., after the parts are assembled into a complete band, then the complete band is inserted into the sclera of the eye). Alternatively, the parts may be "installed separately" (i.e., connected to each other one at a time within the eye) "to form a complete band" within the sclera of the eye. In either case, the individual parts of the scleral expansion band are never used separately. They are always used in a complete, unitary scleral expansion band has the form of a continuous ring.

The '331 Patent refers to a complete band structure in the form of a continuous ring and not to embodiments that have a first end and a second end. "It is also possible to expand the sclera in the region of the ciliary body by positioning a band within or just inside the sclera, the band having a diameter just greater than the natural diameter of the overlying tissue." ('331 Patent,

Column 7, Lines 36-39) (Emphasis added).

The Appellant respectfully points out that the reference to "overlapping ends" in the cited portion of the '331 Patent refers to the "overlapping ends" that only exist during the construction of a complete ring structure. That is, the "overlapping ends" are fastened together during the construction of the complete ring of the scleral expansion band. The existence of "overlapping ends" is a temporary condition that occurs during the construction and adjustment of the circumference of the band. The "overlapping ends" cease to exist after the scleral expansion band has been formed. The circular ring of the scleral expansion band of the '331 Patent would not operate properly if the "overlapping ends" were not joined because there would be asymmetries introduced in the expansion forces generated by such an irregularly shaped expansion band. The Rejected Claims do not claim a prosthesis having "overlapping ends."

The Appellant respectfully submits that the Board has incorrectly interpreted the true nature of the embodiment shown in the '331 Patent. Unless the "overlapping ends" of the '331 Patent reference are connected before the scleral expansion band is placed into operation there is no "embodiment" in the '331 Patent that is capable of performing the desired scleral expansion. If the "overlapping ends" are not connected to form a unitary ring for the scleral expansion band, then the ends can separate and form an irregularly shaped and asymmetric expansion band that will not properly perform the desired scleral expansion.

The '331 Patent does not anticipate the Rejected Claims because the unitary ring of the scleral expansion band of the '331 Patent must be modified in order to read on the Rejected Claims. A prior art device that must be slightly modified to operate in the same manner as the patented

device does not anticipate the patented device. *Topliff v. Topliff*, 145 U.S. 156, 36 L.Ed. 658, 12 S.Ct. 825 (1892) (that a prior art device might, by modification, be made to accomplish the function performed by the patent in question is not sufficient to constitute an anticipation); *Metal Arts Co. v. Fuller Co.*, 389 F.2d 319, 156 USPQ 605 (5th Cir. 1968) (there is no anticipation constituting lack of novelty where modification is necessary to the prior art in order to accomplish the function of the patent in question).

The unitary ring of the scleral expansion band of the '331 Patent must be modified in order to read on the Rejected Claims by breaking the unitary ring of the scleral expansion band into separate segments. This modification disqualifies the '331 Patent as a legally sufficient reference for anticipating the Rejected Claims. Therefore, the '331 Patent does not anticipate the Rejected Claims.

Similarly, the '331 Patent does not anticipate the Rejected Claims because the unitary ring of the scleral expansion band of the '331 Patent must be adjusted in order to read on the Rejected Claims. A prior art device that must be adjusted to operate in the same manner as the patented device does not anticipate the patented device. *Clough v. Gilbert & Barker Mfg.*, 106 U.S. 166, 27 L.Ed. 134, 1 S.Ct. 188 (1882) (that a prior art device might, by adjustment, be made to accomplish the function performed by the patent in question is not sufficient to constitute an anticipation). The unitary ring of the scleral expansion band of the '331 Patent must be adjusted in order to read on the Rejected Claims by breaking the unitary ring of the scleral expansion band into separate segments. This adjustment disqualifies the '331 Patent as a legally sufficient reference for anticipating the Rejected Claims. Therefore, the '331 Patent does not anticipate the Rejected Claims.

To overcome the defense of anticipation, it is only necessary to show some tangible difference between the invention and the prior art, because there is no anticipation unless all of the same elements are found in exactly the same situation and united in the same way to perform the identical function in a single prior art reference. *Del Mar Engineering Laboratories v. Physio-Tronics, Inc.*, 642 F. 2d 1167 (9th Cir. 1987). For all of the reasons set forth above, the '331 Patent does not anticipate the Rejected Claims.

B. THE DISCLOSURE OF THE '331 PATENT IS NOT ENABLING FOR THE CONCEPT OF USING SEPARATE PROSTHESIS SEGMENTS

The Appellant respectfully submits that the '331 Patent is not enabling for the concept of using separate prosthesis segments. Therefore, the '331 Patent is not a legally sufficient reference to anticipate the Rejected Claims.

In order for a prior art patent to constitute an anticipation, the prior art patent must adequately describe the invention that it allegedly anticipates. The enablement standard for anticipation by patenting is generally the same standard as a full enabling disclosure that applies to printed publications. *Chisum on Patents*, § 3.06[1][a], Volume 1, p. 3-187, 2003.

The enabling standard for a prior art publication is that the prior art publication contain within its four corners a sufficient description to enable a person or ordinary skill in the art to make the invention without undue experimentation. *Advanced Display Systems, Inc. v. Kent State University*, 212 F.3d 1272, 1282, 54 USPQ2d 1673, 1679 (Fed.Cir. 2000) ("invalidity by anticipation requires that the four corners of a single, prior art document describe every element of the claimed

invention, either expressly or inherently, such a person of ordinary skill in the art could practice the invention without undue experimentation").

The Appellant respectfully submits that the concept of using separate prosthesis segments in not present, either expressly or inherently, in the '331 Patent. The '331 Patent clearly states that the separate segments of the unitary ring structure are to be fastened together before the unitary ring structure is used. There is absolutely no teaching or suggestion in the '331 Patent to break the unitary ring structure into separate segments. There is absolutely no teaching or suggestion in the '331 Patent to use separate segments of the unitary ring structure to achieve scleral expansion. In fact, the '331 Patent teaches away from the concept of using separate prosthesis segments to achieve scleral expansion. The '331 Patent teaches the use of a unitary ring structure to obtain scleral expansion. For these reasons, the disclosures in the '331 Patent are not enabling for the concept of using separate prosthesis segments to obtain scleral expansion. This means that the '331 Patent does not anticipate the Rejected Claims.

3. CONCLUSION

For the reasons set forth above, the Appellant respectfully requests the Board to reconsider that portion of the Decision on Appeal that affirmed the Examiner's rejection of the Rejected Claims. The Appellant respectfully requests the Board to reverse the Examiner's rejection of Claims 1-7 and Claims 12-17 and order that the rejection of Claims 1-7 and Claims 12-17 under 35 U.S.C. § 102(b) be withdrawn.

SUMMARY

For the reasons given above, the Appellant respectfully requests reconsideration and allowance of the Rejected Claims and that this patent application be passed to issue.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Davis Munck Deposit Account No. 50-0208.

Respectfully submitted,

DAVIS MUNCK, P.C.

Date: Jan. 24, 2005

William A. Munck
Registration No. 39,308

P. O. Drawer 800889
Dallas, Texas 75380
Tel: (972) 628-3600
Fax: (972) 628-3616
email: wmunck@davismunck.com

APPENDIX OF CLAIMS INVOLVED IN THE APPEAL

The text of Claims 1-24 is as follows:

1. A prosthesis that contacts the sclera of an eyeball, said prosthesis comprising a body having a first end and a second end, said body having a planform that expands said contacted sclera to increase the effective working distance of the ciliary muscle of the eyeball.

2. The prosthesis set forth in Claim 1 wherein said body further comprises a top surface that contacts ocular tissue within a pocket surgically formed within the sclera of the eyeball.

3. The prosthesis set forth in Claim 2 wherein said top surface is circumferentially shaped and exerts an outward force on the scleral pocket to elevate the portion of the sclera attached thereto to increase the effective working distance of the ciliary muscle of the eyeball.

4. The prosthesis set forth in Claim 2 wherein said body further comprises a means for stabilizing said prosthesis within said surgically formed pocket within the sclera of the eyeball.

5. The prosthesis set forth in Claim 4 wherein said stabilizing means includes a bottom surface that contacts ocular tissue within said surgically formed pocket.

6. The prosthesis set forth in Claim 5 wherein an ocular tissue contact area of said bottom surface of said body is at least substantially equal to an ocular tissue contact area of said top surface of said body.

7. The prosthesis set forth in Claim 4 wherein said stabilizing means includes at least one of said first end and said second end that fixes said body within said surgically formed pocket.

8. The prosthesis set forth in Claim 7 wherein said at least one of said first end and said second end has a partially concave top surface.

9. The prosthesis set forth in Claim 7 wherein said at least one of said first end and said second end has a partially convex top surface.

10. The prosthesis set forth in Claim 7 wherein said at least one of said first end and said second end has a partially concave bottom surface.

11. The prosthesis set forth in Claim 7 wherein said at least one of said first end and said second end has a partially convex bottom surface.

12. A prosthesis that contacts the sclera of an eyeball, said prosthesis comprising a body having a first end and a second end, said body having a planform that expands said contacted sclera to increase the effective working distance of the ciliary muscle of the eyeball and further means for stabilizing said prosthesis within said surgically formed pocket within the sclera of the eyeball.

13. The prosthesis set forth in Claim 12 wherein said body further comprises a top surface that contacts ocular tissue within a pocket surgically formed within the sclera of the eyeball.

14. The prosthesis set forth in Claim 13 wherein said top surface is circumferentially shaped and exerts an outward force on the scleral pocket to elevate the portion of the sclera attached thereto to increase the effective working distance of the ciliary muscle of the eyeball.

15. The prosthesis set forth in Claim 12 wherein said stabilizing means includes a bottom surface that contacts ocular tissue within said surgically formed pocket.

16. The prosthesis set forth in Claim 15 wherein an ocular tissue contact area of said bottom surface of said body is at least substantially equal to an ocular tissue contact area of said top surface of said body.

17. The prosthesis set forth in Claim 12 wherein said stabilizing means includes at least one of said first end and said second end that fixes said body within said surgically formed pocket.

18. The prosthesis set forth in Claim 17 wherein said at least one of said first end and said second end has a partially concave top surface.

19. The prosthesis set forth in Claim 17 wherein said at least one of said first end and said second end has a partially convex top surface.

20. The prosthesis set forth in Claim 17 wherein said at least one of said first end and said second end has a partially concave bottom surface.

21. The prosthesis set forth in Claim 17 wherein said at least one of said first end and said second end has a partially convex bottom surface.

22. A prosthesis for contacting the sclera of an eyeball, said prosthesis comprising:

a body having at least one end portion which is wider than an incision forming a scleral pocket for containing said prosthesis, a remainder of said body extending from said at least one end portion in a direction substantially perpendicular to a width dimension of said at least one end portion,

a bottom surface of said body having at least one concave region separated from an end of said body by a flat surface,

said at least one concave region having a radius of curvature of approximately five hundred microns,

whereby said prosthesis exerts an outward force on said scleral pocket to elevate a portion of the sclera attached thereto when said prosthesis is disposed within said scleral pocket, and

wherein said at least one end portion is configured to extend beyond said scleral pocket.

23. The prosthesis as set forth in Claim 22, wherein said body includes a major convex surface having a radius of curvature of approximately nine millimeters.

24. The prosthesis as set forth in Claim 22, wherein end portions of said body are sloped.